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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/852,182

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Nut-0003

4884

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05/11/2009

EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

05/11/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/852,182	Applicant(s) HAMMAN ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37,39,42,43,47-49,52,53 and 57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37,39,42,43,47-49,52,53 and 57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed February 4, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 – Obviousness (New Rejections)

1) Claims 37, 39, 43 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ojima et al. (US 7,029,717).

Ojima et al. discloses stabilized sucralose compositions that may be used as a sweetener or incorporated in foods and drugs. The compositions comprise sucralose along with one or more substances such as protein hydrolysates and amino acids. These compositions have a taste improving effect. The substance may comprise no less than 0.01 parts by weight, based on each part by weight of sucralose (col. 10, lines 21-26). Sucralose comprises 1% of the compositions (see examples, for instance example 17). The examples include dry preparations comprising sucralose. The amino acids used in the compositions include any and all amino acids, oligoamino acids (peptide), polyamino acids (polypeptide), and amino acid derivatives. Specifically, such

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amino acids as, hystidine, glycine, alanine, serine, glutamic acid, aspartic acid, lysine, tryptophan, etc: oligoamino acids; and polyamino acids such as polylysine etc. (col. 7, lines 8-32). A specific amino acid includes D,L-methionine (col. 9, line 55). It can be concluded the sucralose is masking the taste of the added substance, thereby encompassing the method claims. It is disclosed that the compositions are made by mixing a substance such as an amino acid with the sucralose, encompassing a compositions "consisting of" an amino acid or mixtures of amino acids and sucralose.

The reference differs from the instant claims insofar as does not specifically disclose the amount of sucralose recited in the instant claims.

The reference discloses the substance (the amino acid) may comprise no less than 0.01 parts by weight, based on each part by weight of sucralose. The prior art does not disclose the exact claimed values of sucralose, 3.9 to about 12 dry weight% of amino acid, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). The claims are obvious over Ojima et al. consistent with the decision of In re Peterson.

2) Claims 37, 39, 42, 43, 47, 48, 49, 52, 53 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fisher et al. (US 3,950,529) in view of Inoue et al. (WO 00/24273 published May 4, 2000, English translation US 7,229,658).

Fisher et al. discloses amino acid formulation for patients with liver disease. The formulations are mixtures of essential and non-essential amino acids. These include L-

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alanine (0.0686-0.103 molar range), L-aspartic acid (0-0.0451 molar range), L-cysteine (0-0.00228 molar range), L-histidine (0.0124-0.0186 molar range), L-isoleucine (0.0549-0.0823), L-leucine (0.067-0.101 molar range), L-lysine (0.0333-0.05 molar range), L-methionine (0.00491-0.0147), L-phenylalanine, L-threonine (0.0228-0.0454 molar range), L-tryptophan (0.000816-0.00441 molar range), and L-valine (0.0574-0.0861 molar range). The reference differs from the instant claims insofar as it does not disclose sucralose in the amino acid compositions.

Inoue et al. disclose sucralose as a masking agent for foods comprising proteins (col. 20, lines 5-20). The amount of sucralose used ranges from 0.0001 to 0.01% by weight relative to the food (col. 24, lines 28-35). It is also used to mask the taste of amino acid or peptides, which are disclosed to have bitter tastes. These amino acids include valine, leucine, methionine and leucine-isoleucine. The sucralose may comprise 0.0001 to 0.5% by weight based on 100% by weight of the composition (col. 44, lines 5-11). Sucralose may also be used to mask the taste of preservatives used in food such as glycine, milt protein, and poly-lysine. Sucralose is added in a concentration ranging from 0.001 to 10 parts by weight of the preservative (col. 68, lines 38-49), which encompasses the limitation that sucralose is 3.9% to about 12 dry weight percent of the amino acid component of the composition. The reference differs from the instant claims insofar as it does not disclose the percentage endpoints for sucralose recited in the instant claims or that the compositions only comprise sucralose and an amino acid.

It would have been obvious to one of ordinary skill in the art to have incorporated sucralose into the compositions of Fisher et al. motivated by the desire to mask the bitter taste associated with amino acids as disclosed by Inoue et al.

The reference discloses sucralose mask the bitter taste of amino acid and is a result effective variable. It would have taken no more than the relative skill of one of ordinary skill in the art to have adjusted the amount of sucralose motivated by the desire to add enough sucralose to mask the bitter taste of the amino acids.

In regards to claim 57, the reference discloses the molar ratio range of amino acid. The prior art does not disclose the exact claimed values of each amino acid, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). The claims are obvious over Fisher et al. in view of Inoue et al. consistent with the decision of In re Peterson.

Claims 37, 39, 42, 43, 47, 48, 49, 52, 53 and 57 are rejected.

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612